FORMPTO-1390(Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR
PG3654USW	09/937232

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/01444	23 February 2000	24 March 1999

TITLE OF INVENTION
VALVE

APPLICANT(S) FOR DO/EO/US
Gregor John McLennan ANDERSON; Marck Andrew HAILEY; David Joseph RUSSELL; James William GODFREY

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). Anderson, Hailey, Russell, Godfrey.
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Copy of PCT Request
Copy of PCT Cover Sheet

Express Mail Label
EL395894976US

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/937232	PCT/EP00/01444	PG3654USW

24. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
☐	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	**$1000.00**
☒	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	**$860.00**
☐	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	**$710.00**
☐	International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	**$690.00**
☐	International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	**$100.00**

ENTER APPROPRIATE BASIC FEE AMOUNT = **$860.00**

Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). **$0.00**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	30 - 20 =	10	x $18.00	**$180.00**
Independent claims	1 - 3 =	0	x $80.00	**$0.00**
Multiple Dependent Claims **(check if applicable)**.			☐	**$0.00**

TOTAL OF ABOVE CALCULATIONS = **$1,040.00**

☐ Applicant claims small entity status. (See 37 CFR 1.27). The fees indicated above are reduced by 1/2. **$0.00**

SUBTOTAL = **$1,040.00**

Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). + **$0.00**

TOTAL NATIONAL FEE = **$1,040.00**

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐ **$0.00**

TOTAL FEES ENCLOSED = **$1,040.00**

Amount to be: refunded	$
charged	$

a. ☐ A check in the amount of _____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. **07-1392** in the amount of **$1,040** to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **07-1392** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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23347
PATENT TRADEMARK OFFICE

SIGNATURE

Christopher P. Rogers
NAME

36,334
REGISTRATION NUMBER

September 24, 2001
DATE

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): **Gregor John McLennan ANDERSON**	Docket No. **PG3654USW**

Serial No.	Filing Date	Examiner	Group Art Unit
To be assigned			

Invention:

VALVE

I hereby certify that this **patent application under 35 USC 371 with corresponding papers**
(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231-0001 on **September 24, 2001**
(Date)

Elaine Martens
(Typed or Printed Name of Person Mailing Correspondence)

Elaine Martens
(Signature of Person Mailing Correspondence)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Anderson et al.	
USPTO Serial No.: To be assigned	Examiner: NYA Art Unit: NYA
USPTO Filing Date: 24 Sept 2001	Docket No.: PG3654USW
Int'l Application No.: PCT/EP00/01444	
Int'l Filing Date: 23 February 2000	
Title: VALVE	

PRELIMINARY AMENDMENT UNDER 35 USC 111

Commissioner for Patents
Washington D.C. 20231

Kindly amend the application as follows. A clean copy of the amended claims is provided in the attached Appendix A. Kindly substitute the clean version of the amended claims (as set forth in Appendix A) for the pending claims having the same claim number. A marked-up version of the claim amendments is set forth as follows. Also, kindly insert the following text relating to lineage at the first paragraph of the specification.

The above identified application is being transmitted herewith for entry in the US National Phase under Chapter II of the PCT for the purpose of adding the priority information. This application is filed pursuant to 35 U.S.C. §371 as a United States.

In the Abstract:

Please substitute the attached Abstract, which has been placed on a separate sheet of paper according to US practice, as required under 37 CFR 1.72(b)

VERSION WITH MARKINGS SHOWING CHANGES MADE TO CLAIMS

1. (Amended) [Valve for an aerosol container, the] A valve comprising:

a valve body; [within said valve body,]

a sealing ring having a rounded stem-receiving portion adapted to engage a valve stem; and [receivable by said sealing ring,]

a valve stem having a dispensing passage[, the valve stem being] adapted to be receivable by the sealing ring and adapted to slidingly engage [slidably movable within] the sealing ring [from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage,

wherein the sealing ring is shaped such as to reduce the contact area between the sealing ring and the valve stem].

2. (Amended) [Valve] The valve according to claim 1, wherein the area of contact between the rounded stem-receiving portion of the sealing ring and the valve stem is less than 90% of [what] the area of contact [would be if the sealing ring had square-cut edges] for a non-rounded sealing ring.

3. (Amended) [Valve] The valve according to [either of claims 1 or 2] claim 1, wherein the sealing ring is [formable] made by a moulding process.

4. (Amended) [Valve] A valve according to claim 3 wherein the moulding process is injection moulding.

5. (Amended) [Valve] A valve according to claim 3 wherein the moulding process is compression moulding.

6. (Amended) [Valve] A valve according to claim 3 wherein the moulding process is transfer moulding.

7. (Amended) [Valve] The valve according to [any of claims 1 to 6] claim 1, wherein the sealing ring is [not movable] adapted to be fixedly stationary relative to the valve body.

8. (Amended) [Valve] The valve according to claim 7, wherein the sealing ring is [held] adapted to be fixedly stationary within a cavity in the valve body.

9. (Amended) [Valve] The valve according to [any of claims 1 to 8] claim 1, wherein the rounded stem-receiving [part] portion of the sealing ring [has] includes at least one rounded edge.

10. (Amended) [Valve] The valve according to any of [claims 1 to 9] claim 1, wherein the rounded stem-receiving [part] portion of the sealing ring [presents] includes a lobed surface [to the stem].

11. (Amended) [Valve] The valve according to claim 10, wherein the lobed surface [and the stem-receving part of the stem define] includes one or more wells.

12. (Amended) [Valve] The valve according to claim 11, wherein [said] the one or more wells [comprise] includes a lubricant material therein.

13. (Amended) [Valve] The valve according to [any of claims 1 to 12] claim 1, wherein the valve body [has] includes a metering chamber, a sampling chamber, and [therebetween is provided]

further including a second sealing ring [within which the stem is] adapted to slidably [movable] engage the stem, and,

wherein the valve stem [having] includes a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, [and]

wherein, in the valve-open position, the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, and,

wherein the second sealing ring [is shaped such as to reduce the contact area between the second sealing ring and the valve stem] includes a second rounded stem-receiving portion adapted to engage the stem.

14. (Amended) [Valve] The valve according to claim 13, wherein the area of contact between the second [sealing ring] rounded stem-receiving portion and the valve stem is less than 90% of [what] the area of contact [would be if the second] between a non-rounded sealing ring and the stem [had square-cut edges].

15. (Amended) [Valve] The valve according to [either of claims 13 or 14] claim 1, wherein the second sealing ring is [formable] made by a moulding process.

16. (Amended) [Valve] The valve according to claim 15 wherein the moulding process is injection moulding.

17. (Amended) [Valve] The valve according to claim 15 wherein the moulding process is compression moulding.

18. (Amended) [Valve] The valve according to claim 15 wherein the moulding process is transfer moulding.

19. (Amended) [Valve] The valve according to [any of claims 13 to 18] claim 10, wherein the second sealing ring is [not movable] adapted to be fixedly stationary relative to the valve body.

20. (Amended) [Valve] The valve according to claim 19, wherein the second sealing ring is [held] adapted to be fixedly stationary within a cavity in

the valve body.

21. (Amended) [Valve] The valve according to [any of claims 13 to 20] claim 14, wherein the second stem-receiving [part] portion [of the second sealing ring has] includes at least one rounded edge.

22. (Amended) [Valve] The valve according to [any of claims 13 to 21] claim 15, wherein the second stem-receiving [part of the second sealing ring presents] portion includes a lobed surface [to the stem].

23. (Amended) [Valve] The valve according to claim 22, wherein the lobed surface [and the stem-receving part of the stem define] includes one or more wells.

24. (Amended) [Valve] The valve according to claim 23, wherein [said] the one or more wells [contain] include a lubricant material [therein].

25. (Amended) [Valve] The valve according to [any of claims 1 to 24] claim 1, wherein the sealing ring comprises an elastomeric material.

26. (Amended) [Valve] The valve according to [any of claims 13 to 25] claim 13, wherein the second sealing ring comprises [an] a second elastomeric material.

27. (Amended) [Valve] The valve according to [claims 25 and 26] claim 26 wherein the first and/or second elastomeric material is selected from the group consisting of [(a)] a thermoplastic elastomer comprising a copolymer of about 80 to about 95 mole percent ethylene and a total of about 5 to about 20 [percent] mole percent of one or more of 1-butene, 1-hexene and 1-octene; [(b)] a styrene-ethylene/butylene-styrene block copolymer; [(c)] an ethylene propylene diene rubber [(EPDM)]; [(d)] a thermoplastic elastomer blend of [EPDM] an ethylene propylene diene rubber dispersed in a

polypropylene polyethylene matrix; [(e)] a butyl polyethylene; [(f)] a butyl-polypropylene; and any mixtures thereof.

28. (Amended) [Valve] A valve according to [any of claims 1 to 27] claim 27, wherein the first sealing ring additionally comprises a lubricant material.

29. (Amended) [Valve] A valve according to [claims 13 to 28] claim 13, wherein the second sealing ring additionally comprises a second lubricant material.

30. (Amended) [Valve] A valve according to [any of claims 1 to 29] claim 1, wherein the stem comprises a third lubricant material.

Kindly cancel claims 31-34 without prejudice to the filing of claims directed to the subject matter therein in the instant application or in any continuing or divisional applications.

REMARKS

Claims 1-30 are pending. For the above reasons, Applicants respectfully traverse the rejections and objections set forth in the outstanding Office Action and request that they be withdrawn. Applicants respectfully contend that the application is in condition for allowance and requests the same. The Examiner is invited to contact the undersigned should there be any questions or concerns.

Respectfully submitted,

Date: 24 Sept 2001

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Appendix A

1. (Amended) A valve comprising:

a valve body;

a sealing ring having a rounded stem-receiving portion adapted to engage a valve stem; and

a valve stem having a dispensing passage adapted to be receivable by the sealing ring and adapted to slidingly engage the sealing ring.

2. (Amended) The valve according to claim 1, wherein the area of contact between the rounded stem-receiving portion of the sealing ring and the valve stem is less than 90% of the area of contact for a non-rounded sealing ring.

3. (Amended) The valve according to claim 1, wherein the sealing ring is made by a moulding process.

4. (Amended) A valve according to claim 3 wherein the moulding process is injection moulding.

5. (Amended) A valve according to claim 3 wherein the moulding process is compression moulding.

6. (Amended) A valve according to claim 3 wherein the moulding process is transfer moulding.

7. (Amended) The valve according to claim 1, wherein the sealing ring is adapted to be fixedly stationary relative to the valve body.

8. (Amended) The valve according to claim 7, wherein the sealing ring is adapted to be fixedly stationary within a cavity in the valve body.

9. (Amended) The valve according to claim 1, wherein the rounded stem-receiving portion of the sealing ring includes at least one rounded edge.

10. (Amended) The valve according to any of claim 1, wherein the rounded stem-receiving portion of the sealing ring includes a lobed surface.

11. (Amended) The valve according to claim 10, wherein the lobed surface includes one or more wells.

12. (Amended) The valve according to claim 11, wherein the one or more wells includes a lubricant material therein.

13. (Amended) The valve according to claim 1, wherein the valve body includes a metering chamber, a sampling chamber, and

further including a second sealing ring adapted to slidably engage the stem, and,

wherein the valve stem includes a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage,

wherein, in the valve-open position, the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, and,

wherein the second sealing ring includes a second rounded stem-receiving portion adapted to engage the stem.

14. (Amended) The valve according to claim 13, wherein the area of contact between the second rounded stem-receiving portion and the valve stem is less than 90% of the area of contact between a non-rounded sealing ring and the stem.

15. (Amended) The valve according to claim 1, wherein the second sealing ring is made by a moulding process.

16. (Amended) The valve according to claim 15 wherein the moulding process is injection moulding.

17. (Amended) The valve according to claim 15 wherein the moulding process is compression moulding.

18. (Amended) The valve according to claim 15 wherein the moulding process is transfer moulding.

19. (Amended) The valve according to claim 10, wherein the second sealing ring is adapted to be fixedly stationary relative to the valve body.

20. (Amended) The valve according to claim 19, wherein the second sealing ring is adapted to be fixedly stationary within a cavity in the valve body.

21. (Amended) The valve according to claim 14, wherein the second stem-receiving portion includes at least one rounded edge.

22. (Amended) The valve according to claim 15, wherein the second stem-receiving portion includes a lobed surface.

23. (Amended) The valve according to claim 22, wherein the lobed surface includes one or more wells.

24. (Amended) The valve according to claim 23, wherein the one or more wells include a lubricant material.

25. (Amended) The valve according to claim 1, wherein the sealing

ring comprises an elastomeric material.

26. (Amended) The valve according to claim 13, wherein the second sealing ring comprises a second elastomeric material.

27. (Amended) The valve according to claim 26 wherein the first and/or second elastomeric material is selected from the group consisting of a thermoplastic elastomer comprising a copolymer of about 80 to about 95 mole percent ethylene and a total of about 5 to about 20 mole percent of one or more of 1-butene, 1-hexene and 1-octene; a styrene-ethylene/butylene-styrene block copolymer; an ethylene propylene diene rubber; a thermoplastic elastomer blend of an ethylene propylene diene rubber dispersed in a polypropylene polyethylene matrix; a butyl polyethylene; a butyl-polypropylene; and any mixtures thereof.

28. (Amended) A valve according to claim 27, wherein the first sealing ring additionally comprises a lubricant material.

29. (Amended) A valve according to claim 13, wherein the second sealing ring additionally comprises a second lubricant material.

30. (Amended) A valve according to claim 1, wherein the stem comprises a third lubricant material.

Valve

This invention relates to a valve for an aerosol container with the aid of which a quantity of the contents thereof can be dispensed. The invention has particular application to the dispensing of metered doses of medicaments, though it is applicable to the dispensing of aerosols generally.

Containers for aerosol formulations commonly comprise a vial body coupled to a valve. The valve comprises a valve stem through which the formulation is dispensed. Generally the valve includes a rubber valve seal intended to allow reciprocal movement of the valve stem while preventing leakage of propellant from the container.

It has been found that in some conventional devices the valve stem tends to stick, pause, or drag during the actuation cycle with the result that the valve stem may not move smoothly, particularly when released. This may be partly caused by the drug sedimenting or precipitating out of the drug-propellant suspension or solution formulation and depositing on the internal valve components, the presence of drug on the sliding interface creating increased friction during operation.

Prior art seals generally comprise a rubber ring formed by stamping out a ring shape from a sheet of rubber material. The ring aperture, thus, inevitably has square-cut edges which present a relatively high area of contact between the seal and the stem. Furthermore, when the valve stem is moved in such square-cut seals the seal deforms in such a way that the surface area, and hence the frictional contact area, between the seal and stem increases.

The Applicants have now found that the above described problem may be ameliorated without compromising sealing performance if the valve seal is shaped such as to reduce the area of contact between the seal and the stem. If a manufacturing process based upon moulding is employed a ring may be formed having a ring aperture with rounded or otherwise shaped edges. When such a rounded or shaped-edge ring is used as a valve seal the area of contact between the seal and the stem is less than that for a ring of equivalent thickness

having square-cut edges. On movement of the stem within the seal there is also less tendency for the seal to deform such as to increase the contact area between the seal and the stem.

According to the present invention there is provided a valve for an aerosol container, the valve comprising a valve body; within said valve body, a sealing ring; and receivable by said sealing ring, a valve stem having a dispensing passage, the valve stem being slidably movable within the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage, wherein the sealing ring is shaped such as to reduce the contact area between the sealing ring and the valve stem.

Preferably, the area of contact between the sealing ring and the valve stem is less than 90%, more preferably less than 70%, most preferably less than 50% of what the area of contact would be if the stem-receiving aperture of the sealing ring had square-cut edges.

Preferably, the sealing ring is formable by a moulding process.

Preferably, the moulding process is injection moulding.

Alternatively, the moulding process is compression moulding.

Alternatively, the moulding process is transfer moulding.

Preferably, the sealing ring is not movable relative to the valve body, that is to say it is somehow fixed thereto. More preferably, the sealing ring is held within a cavity in the valve body.

In one aspect, the stem-receiving part of the sealing ring has at least one rounded edge, preferably all stem-receiving edges are rounded.

In another aspect, the stem-receiving part of the sealing ring presents a lobed surface to the stem. That is to say the surface comprises one or more lobe

features. Preferably, the lobed surface and the stem-receiving part of the stem define one or more wells. More preferably, the one or more wells contain lubricant material therein.

Preferably, the valve is a metering valve in which the valve body has a metering chamber, a sampling chamber and therebetween is provided a second sealing ring within which the stem is slidably movable, the valve stem having a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, and in the valve-open position the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, wherein the second sealing ring is shaped such as to reduce the contact area between the second sealing ring and the valve stem.

Preferably, the area of contact between the second sealing ring and the valve stem is less than 90%, more preferably less than 70%, most preferably less than 50% of what the area of contact would be if the stem-receiving aperture of the second sealing ring had square-cut edges.

Preferably, the sealing ring and any second sealing ring is formable by a moulding process.

Preferably, the moulding process is injection moulding.

Alternatively, the moulding process is compression moulding.

Alternatively, the moulding process is transfer moulding.

Preferably, the second sealing ring is not movable relative to the valve body. More preferably, the second sealing ring is held within a cavity in the valve body.

In one aspect, the stem-receiving part of the second sealing ring has at least one rounded edge, preferably all stem-receiving edges are rounded.

In another aspect, the stem-receiving part of the second sealing ring presents a lobed surface to the stem. Preferably, the lobed surface and the stem-receiving part of the stem define one or more wells. More preferably, the one or more wells contain lubricant material therein.

Preferably the sealing ring and/or second sealing ring comprises an elastomeric material. The ring is typically resiliently deformable.

The elastomeric material may either comprise a thermoplastic elastomer (TPE) or a thermoset elastomer which may optionally be cross-linked. The sealing ring may also comprise a thermoplastic elastomer blend or alloy in which an elastomeric material is dispersed in a thermoplastic matrix. The elastomers may optionally additionally contain conventional polymer additives such as processing aids, colorants, tackifiers, lubricants, silica, talc, or processing oils such as mineral oil in suitable amounts.

Suitable thermoset rubbers include butyl rubbers, chloro-butyl rubbers, bromo-butyl rubbers, nitrile rubbers, silicone rubbers, flurosilicone rubbers, fluorocarbon rubbers, polysulphide rubbers, polypropylene oxide rubbers, isoprene rubbers, isoprene-isobutene rubbers, isobutylene rubbers or neoprene (polychloroprene) rubbers.

Suitable thermoplastic elastomers comprise a copolymer of about 80 to about 95 mole percent ethylene and a total of about 5 to about 20 mole percent of one or more comonomers selected from the group consisting of 1-butene, 1-hexene, and 1-octene as known in the art. Two or more such copolymers may be blended together to form a thermoplastic polymer blend.

Another suitable class of thermoplastic elastomers are the styrene-ethylene/ butylene-styrene block copolymers. These copolymers may additionally comprise a polyolefin (e.g. polypropylene) and a siloxane.

Thermoplastic elastomeric material may also be selected from one or more of the following: polyester rubbers, polyurethane rubbers, ethylene vinyl acetate

rubber, styrene butadiene rubber, copolyether ester TPE, olefinic TPE, polyester amide TPE and polyether amide TPE.

Other suitable elastomers include ethylene propylene diene rubber (EPDM). The EPDM may be present on its own or present as part of a thermoplastic elastomer blend or alloy, e.g. in the form of particles substantially uniformly dispersed in a continuous thermoplastic matrix (e.g. polypropylene or polyethylene). Commercially available thermoplastic elastomer blend and alloys include the SANTOPRENE™ elastomers. Other suitable thermoplastic elastomer blends include butyl-polyethylene (e.g. in a ratio ranging between about 2:3 and about 3:2) and butyl-polypropylene.

The above-mentioned elastomeric materials can be prepared using methods known to those skilled in the art.

Preferably, the sealing ring and/or the second sealing ring additionally comprises lubricant material. Suitably, the sealing ring and/or the second sealing ring comprises up to 30%, preferably from 5 to 20% lubricant material.

Preferably, the stem comprises lubricant material. Suitably, the valve stem comprises up to 30%, preferably from 5 to 20% lubricant material.

The term 'lubricant' herein means any material which reduces friction between the valve stem and seal. Suitable lubricants include silicone oil or a fluorocarbon polymer such as polytetrafluoroethane (PTFE) or fluoroethylene propylene (FEP).

Lubricant can be applied to the stem, sealing ring or second sealing ring by any suitable process including coating and impregnation, such as by injection or a tamponage process.

According to another aspect of the present invention, there is provided an aerosol container comprising a valve as described hereinabove.

Preferably, the aerosol container comprises a suspension of a medicament in a propellant.

Preferably, the propellant is liquefied HFA134a or HFA-227 or mixtures thereof.

Preferably, the medicament is selected from albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate and ipratropium bromide and salts or solvates thereof and any combination thereof.

The invention will now be described further with reference to the accompanying drawing in which:

Figure 1 is a section through a metering valve according to the invention;

Figure 2 is a close-up sectional view of a seal-stem contact point in a valve according to the invention;

Figure 3 is a close-up sectional view of a seal-stem contact point in a valve according to the invention;

Figure 4a is a close-up sectional view of a seal-stem contact point in a prior art valve in a rest position; and

Figure 4b is a close-up sectional view of a seal-stem contact point in the valve of Figure 4a in an active position.

A valve according to the invention is shown in Figure 1 and comprises a valve body 1 sealed in a ferrule 2 by means of crimping, the ferrule itself being set on the neck of a container (not shown) with interposition of a gasket 3 in a well-known manner. The container is loadable with a suspension of medicament, such as salmeterol xinafoate in liquid propellant HFA134a.

The valve body 1 is formed at its lower part with a metering chamber 4, and its upper part with a sampling chamber 5 which also acts as a housing for a return spring 6. The words "upper" and "lower" are used for the container when it is in a use orientation with the neck of the container and valve at the lower end of the container which corresponds to the orientation of the valve as shown in Figure 1. Inside the valve body 1 is disposed a valve stem 7, a part 8 of which extends outside the valve through lower stem seal 9 and ferrule 2. The stem part 8 is formed with an inner axial or longitudinal canal 10 opening at the outer end of the stem and in communication with a radial passage 11.

The upper portion of stem 7 has a diameter such that it can pass slidably through an opening in an upper stem seal 12 and will engage the periphery of that opening sufficiently to provide a seal. The stem seals 9 and 12 are made by a moulding process and have rounded points of contact with the valve stem 7. Upper stem seal 12 is held in position against a step 13 formed in the valve body 1 between the said lower and upper parts by a sleeve 14 which defines the metering chamber 4 between lower stem seal 9 and upper stem seal 12. The valve stem 7 has a passage 15 which, when the stem is in the inoperative position shown, provides a communication between the metering chamber 4 and sampling chamber 5, which itself communicates with the interior of the container via orifice 16 formed in the side of the valve body 1.

Valve stem 7 is biased downwardly to the inoperative position by return spring 6 and is provided with a shoulder 17 which abuts against lower stem seal 9. In the inoperative position as shown in Figure 1 shoulder 17 abuts against lower stem seal 9 and radial passage 11 opens below lower stem seal 9 so that the metering chamber 4 is isolated from canal 10 and suspension inside cannot escape.

A ring 18 having a "U" shaped cross section extending in a radial direction is disposed around the valve body below orifice 16 so as to form a trough 19 around the valve body. As seen in Figure 1 the ring is formed as a separate component having an inner annular contacting rim of a diameter suitable to provide a friction fit over the upper part of valve body 1, the ring seating against

step 13 below the orifice 16. However, the ring 18 may alternatively be formed as an integrally moulded part of valve body 1.

To use the device the container is first shaken to homogenise the suspension within the container. The user then depresses the valve stem 7 against the force of the spring 6. When the valve stem is depressed both ends of the passage 15 come to lie on the side of upper stem seal 12 remote from the metering chamber 4. Thus a dose is metered within the metering chamber. Continued depression of the valve stem will move the radial passage 11 into the metering chamber 4 while the upper stem seal 12 seals against the valve stem body. Thus, the metered dose can exit through the radial passage 11 and the outlet canal 10.

Releasing the valve stem causes it to return to the illustrated position under the force of the spring 6. The passage 15 then once again provides communication between the metering chamber 4 and sampling chamber 5. Accordingly, at this stage liquid passes under pressure from the container through orifice 16, through the passage 15 and thence into the metering chamber 4 to fill it.

Figure 2 shows a cut-away detail of a seal-stem contact point of a valve herein. The upright valve stem 108 which has a circular cross-section is sealingly contacted by a sealing ring 112. The ring aperture 130 of the sealing ring 112 has rounded edges. It may be understood that the area of contact of the ring 112 with the stem 108 is less than it would be if the ring 112 had square-cut edges. When the stem 108 is moved upwards, the ring 112 will tend to flex into free-space 140.

Figure 3 shows a cut-away detail of a seal-stem contact point of a second valve herein. The upright valve stem 208 which has a circular cross-section is sealingly contacted by a sealing ring 212. The ring aperture of the sealing ring 212 is edged by two rounded lobes 230, 232. The area of contact of the ring 212 with the stem 208 is less than it would be if the ring 212 had square-cut edges. When the stem 208 is moved within the ring 212, the ring 212 will tend to flex into free-space 240 and well 242. The well 242 may be wholly or partially filled with a lubricant material.

Figures 4a and 4b show a cut-away detail of a seal-stem contact point of a prior art valve, wherein Figure 4a shows a rest configuration and Figure 4b shows the configuration when the valve is in an active position. The upright valve stem 308 which has a circular cross-section is sealingly contacted by a sealing ring 312. The ring aperture 330 of the sealing ring 312 has square-cut edges 330. When the stem is moved upwards as shown in Figure 4b, the ring 312 is deformed and spreads out such that the area of contact between the ring 312 and the stem 308 is increased. The frictional contact between the ring 312 and stem is thus, also increased.

It may be appreciated that a number of different configurations of the sealing ring are possible, in addition to those described in Figures 2 and 3, in which the contact area between the sealing ring and the valve stem is reduced. One possible configuration is similar to that shown in Figure 3 but the ring aperture is edged by more than 2 lobes. Another possible configuration has a sealing ring aperture with straight tapered edges leading to a point (such that its cross section is triangular in shape) which has reduced contact with the valve stem compared to straight cut edges. A lobed version of this sealing ring is also possible wherein there are two or more lobes each tapered to a point. A further configuration which reduces the contact area with the valve stem has sections of the top and bottom sides of the ring aperture cut away to leave a smaller projecting portion to form a seal with the valve stem. The projecting portion may have straight cut or shaped edges. Cutting one or more grooves or small channels in the non stem-receiving surfaces of the sealing ring provides space for the stem-receiving part of the sealing ring to move into upon movement of the valve stem, resulting in reduced deformation and friction at the contact surface with the valve stem.

It may be appreciated that any of the parts of the metering valve which contact the medicament suspension may be coated with materials such as fluoropolymer materials which reduce the tendency of medicament to adhere thereto. Suitable fluoropolymers include polytetrafluoroethylene (PTFE) and fluoroethylene propylene (FEP). Any movable parts may also have coatings applied thereto which enhance their desired movement characteristics. Frictional coatings may

therefore be applied to enhance frictional contact and lubricants used to reduce frictional contact as necessary.

The aerosol container and valve of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders such as asthma and chronic obstructive pulmonary disease (COPD).

Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro-α-[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate, and ipratropium bromide and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the

free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

PG3654-PCT

Claims

1. Valve for an aerosol container, the valve comprising a valve body; within said valve body, a sealing ring; and receivable by said sealing ring, a valve stem having a dispensing passage, the valve stem being slidably movable within the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage, wherein the stem-receiving part of the sealing ring has at least one rounded or shaped edge such as to reduce the contact area between the sealing ring and the valve stem.

2. Valve according to claim 1, wherein the area of contact between the sealing ring and the valve stem is less than 90% of what the area of contact would be if the sealing ring had square-cut edges.

3. Valve according to either of claims 1 or 2, wherein the sealing ring is formable by a moulding process.

4. Valve according to claim 3 wherein the moulding process is injection moulding.

5. Valve according to claim 3 wherein the moulding process is compression moulding.

6. Valve according to claim 3 wherein the moulding process is transfer moulding.

7. Valve according to any of claims 1 to 6, wherein the sealing ring is not movable relative to the valve body.

8. Valve according to claim 7, wherein the sealing ring is held within a cavity in the valve body.

9. Valve according to any of claims 1 to 8, wherein the stem-receiving part of the sealing ring has fully rounded edges.

10. Valve according to any of claims 1 to 9, wherein the stem-receiving part of the sealing ring presents a lobed surface to the stem.

11. Valve according to claim 10, wherein the lobed surface and the stem-receiving part of the stem define one or more wells.

12. Valve according to claim 11, wherein said one or more wells contain lubricant material therein.

13. Valve according to any of claims 1 to 12, wherein the valve body has a metering chamber, a sampling chamber and therebetween is provided a second sealing ring within which the stem is slidably movable, the valve stem having a transfer passage such that in the valve-closed position the dispensing passage is isolated from the metering chamber and the metering chamber is in communication with the sampling chamber via said transfer passage, and in the valve-open position the dispensing passage is in communication with the metering chamber and the transfer passage is isolated from the metering chamber, wherein the stem-receiving part of the second sealing ring has at least one rounded or shaped edge such as to reduce the contact area between the second sealing ring and the valve stem.

14. Valve according to claim 13, wherein the area of contact between the second sealing ring and the valve stem is less than 90% of what the area of contact would be if the second sealing ring had square-cut edges.

15. Valve according to either of claims 13 or 14, wherein the second sealing ring is formable by a moulding process.

16. Valve according to claim 15 wherein the moulding process is injection moulding.

17. Valve according to claim 15 wherein the moulding process is compression moulding.

18. Valve according to claim 15 wherein the moulding process is transfer moulding.

19. Valve according to any of claims 13 to 18, wherein the second sealing ring is not movable relative to the valve body.

20. Valve according to claim 19, wherein the second sealing ring is held within a cavity in the valve body.

21. Valve according to any of claims 13 to 20, wherein the stem-receiving part of the second sealing ring has at least one rounded edge.

22. Valve according to any of claims 13 to 21, wherein the stem-receiving part of the second sealing ring presents a lobed surface to the stem.

23. Valve according to claim 22, wherein the lobed surface and the stem-receiving part of the stem define one or more wells.

24. Valve according to claim 23, wherein said one or more wells contain lubricant material therein.

25. Valve according to any of claims 1 to 24 wherein the sealing ring comprises an elastomeric material.

26. Valve according to any of claims 13 to 25 wherein the second sealing ring comprises an elastomeric material.

27. Valve according to claims 25 and 26 wherein the elastomeric material is selected from the group consisting of
(a) a thermoplastic elastomer comprising a copolymer of about 80 to about 95 mole percent ethylene and a total of about 5 to about 20 percent mole percent of one or more of 1-butene, 1-hexene and 1-octene;
(b) a styrene-ethylene/butylene-styrene block copolymer;
(c) an ethylene propylene diene rubber (EPDM)
(d) a thermoplastic elastomer blend of EPDM dispersed in a polypropylene or polyethylene matrix;
(e) a butyl polyethylene;

(f) a butyl-polypropylene; and any mixtures thereof.

28. Valve according to any of claims 1 to 27, wherein the sealing ring additionally comprises lubricant material.

29. Valve according to any of claims 13 to 28, wherein the second sealing ring additionally comprises lubricant material.

30. Valve according to any of claims 1 to 29, wherein the stem comprises lubricant material.

31. Aerosol container comprising a valve according to any of claims 1 to 30.

32. Aerosol container according to claim 31 comprising a suspension of a medicament in a propellant.

33. Aerosol container according to claim 32, wherein, the propellant is liquefied HFA134a or HFA-227 or mixtures thereof.

34. Aerosol container according to either of claims 32 or 33, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, ipratropium bromide and salts or solvates thereof and any combination thereof.

VALVE

Abstract

There is provided a valve for an aerosol container. The valve comprises a valve body(1); within said valve body(1), a sealing ring (112) and receivable by the sealing ring (112), a valve stem (108) having a dispensing passage (10,11). The valve stem (108) is slidably movable within the sealing ring (112) from a valve-closed position to a valve-open position in which the interior of the valve body (1) is in communication with the dispensing passage (10,11). The sealing ring (112) is shaped such as to reduce the contact area between the sealing ring (112) and the valve stem (108). Preferably, the valve is metering valve.

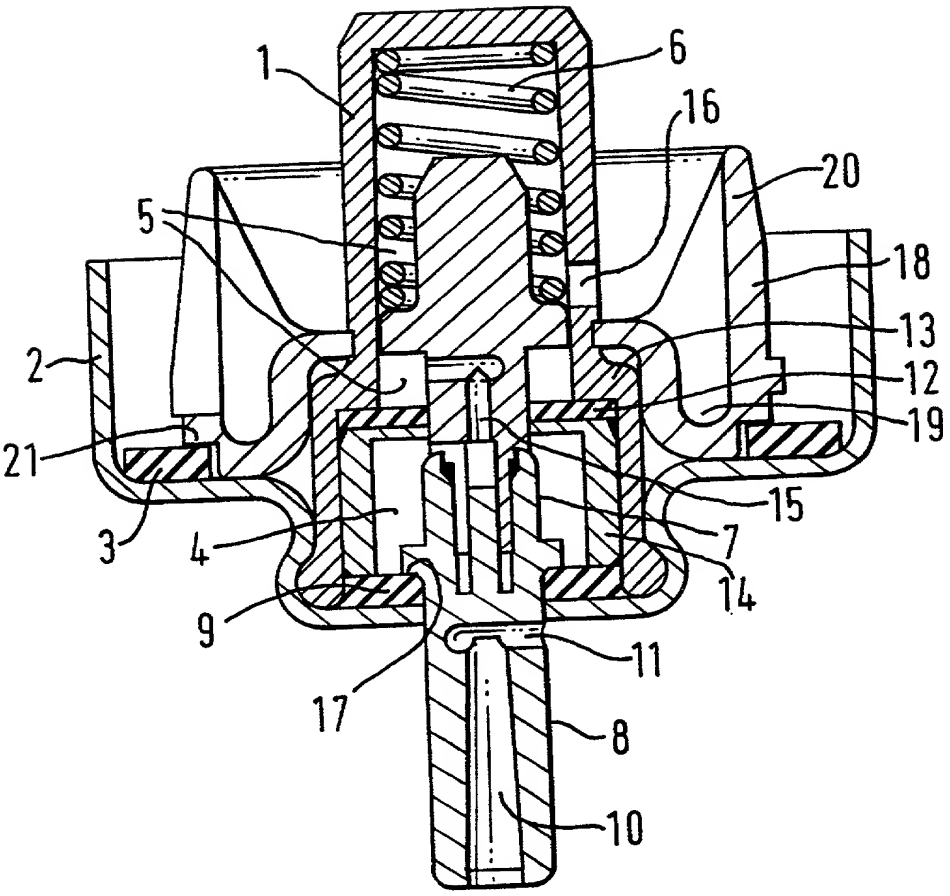


FIG. 1.

FIG. 2.

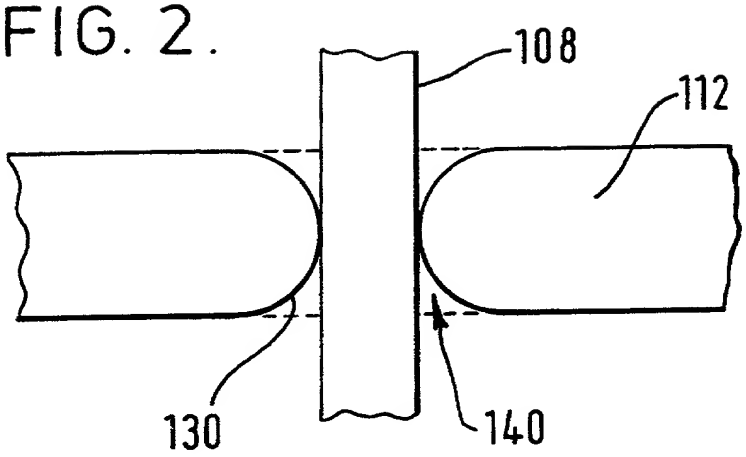


FIG. 3.

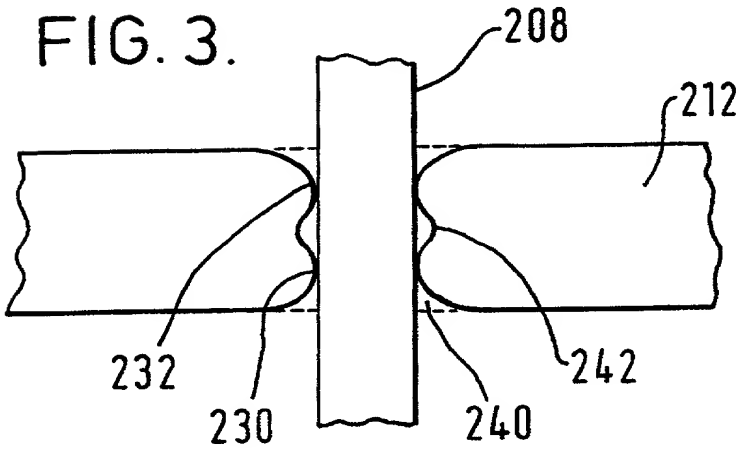


FIG. 4a.

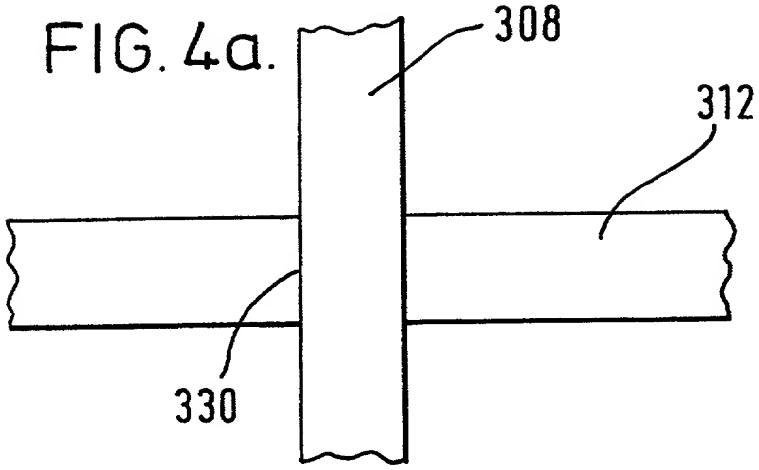
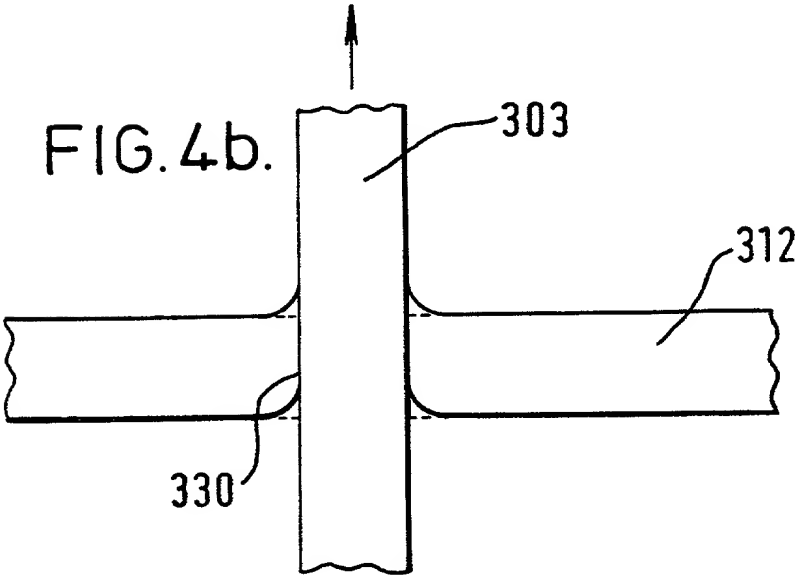


FIG. 4b.



COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION WITH POWER OF ATTORNEY

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PG3654USW
First Names Inventor: Gregor John McLennan ANDERSON
Complete if known: App No.:
Filing Date
Group Art Unit:

( ) Declaration submitted with initial filing or

( )Declaration submitted after initial filing (surcharge required 37CFR1.16(e))

As below named inventor. I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

VALVE

the specification of which (check only one item below):

[ ]is attached hereto.
OR
[x] was filed on **23 February 2000** as United States application Serial No. _____ or **PCT** International

Application Number **PCT/EP00/01444** filed and was amended on (MM/DD/YYYY) _____(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35, U.S.C. §119 (a)-(d) or §365(b) of any foreign applications(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

Prior Foreign Application Number (s)	Country	Foreign Filing Date (MM/DD/YYYY))	PRIORITY CLAIMED
1 9906640.9	GB	March 24, 1999	X
2.			
3.			
4.			
5.			

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date (MM/DD/YYYY)	
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2.		
3.		
4.		

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Continued

ATTORNEY'S DOCKET NUMBER: PG3654USW

I hereby claim the benefit under 35, U.S.C. §120 of any United States application or §365(c) of any PCT international application designating the United States of America that is listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. PARENT APPLICATION or PCT PARENT APPLICATION

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	STATUS (Check one) PATENTED	PENDING	ABANDONED

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith. (List name and registration number)

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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DECLARATION FOR "371" APPLICATION

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